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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,894	08/04/2003	Yung-Feng Nien	ASI 128	2895

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EXAMINER

KOSSON, ROSANNE

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 11/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/632,894

Applicant(s)

NIEN ET AL.

Examiner

Rosanne Kosson

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 5-16 is/are rejected.
- 7) ☒ Claim(s) 3 and 4 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The amendments filed on September 30, 2004 and October 28, 2004 have been received and entered.

The text of those sections of Title 35, U.S. code, not included in this action can be found in a prior office action.

Claims 1-16 are pending and are examined on the merits.

Allowable Subject Matter

Claims 3 and 4 are objected to as being dependent upon rejected base claims, but would be allowable if rewritten in independent form including all of the limitations of the base claims and any intervening claims. The prior art does not teach or reasonably suggest a device or method for capturing biological samples in which, when a tissue sample is placed between a slide on the top side and a working platform on the bottom side, the cells of interest may be separated from the tissue sample by cutting with an air knife.

Claim Rejections - 35 USC § 103

Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein et al. (WO 99/39176). Goldstein discloses a device for capturing biological tissue samples produced by laser capture microdissection. The device comprises a contactless cutting apparatus for cutting biological tissues with a laser beam focused to

Art Unit: 1651

a point (42, 46), a microfeeding mechanism that drives a working platform (38, 40- the stage holding slide 32) on which the tissue samples (34) are supported, an impact lever and linking head providing a downward force (62) that pushes a tissue sample through a hole and into a collection vessel (66), a thin, flat protecting means (18) for covering tissue samples and holding them above the collection vessels, and a clear slide for holding the tissue samples (32) (see Figures 1 and 11; p.7, lines 30-35; p. 10, lines 20-25; p. 13, lines 13-26).

The reference also discloses a method for capturing biological tissue samples using the device. The method comprises labeling a profile of a sample to be captured, controlling a drive means to drive a working platform for capturing the sample, and cutting it with a contactless cutting means (see Abstract and p. 1, line 24, to p. 2, line 5). The method also comprises driving the working platform to position the sample below an impact lever linking head and impact lever. The impact lever and impact lever linking head apply a downward force to pass the sample through a hole and into a collection vessel (see Figures 1 and 11; p.7, lines 30-35; and p. 13, lines 13-26). The reference does not disclose placing the tissue sample on a biological slide, inverting the slide and fixing the slide on a working platform. Nevertheless, in the reference, as in Applicants' invention, the tissue sample is located on a slide affixed to a working platform (compare Applicants' Figure 1 to Figure 1 in Goldstein) before it is labeled and cut. But, preparing an LCM tissue sample attached to a slide is routine in the pertinent art, and the manner of preparing such slides is clearly a result-effective parameter routinely optimized by the artisan of ordinary skill at the time of Applicants' invention. The preparation of slides for

performing the method of the instant invention, as recited in claim 1, clearly would have been a matter of routine optimization on the part of the artisan of ordinary skill and therefore obvious under § 103(a). Therefore, a holding of obviousness is required.

All of Applicants' arguments regarding this rejection have been fully considered but are not persuasive of error. It is noted that Applicants have amended the claims to recite that, in the device (claim 2), a tissue sample is placed between a slide, as the top layer, and a working platform, as the bottom layer. A tissue sample protecting layer containing a sampling hole is located below the working platform, and a sampling mortar is located below the hole. After cutting the desired cells from the tissue sample with a microdissection laser, the corresponding area of the overlaying slide is contacted with an impact lever, which force pushes the sample through the hole and into the mortar. Similarly, it is noted that amended claim 1 recites a method for capturing a biological tissue sample in which a tissue sample is placed between a slide, as the top layer, and a working platform, as the bottom layer. A tissue sample protecting layer containing a sampling hole is located below the working platform, and a sampling mortar is located below the hole. After cutting the desired cells from the tissue sample with a microdissection laser, the corresponding area of the overlaying slide is contacted with an impact lever, which force pushes the sample through the hole and into the mortar.

With respect to Applicants' comment that their invention is novel and inventive because the tissue sample protecting layer prevents contaminants from falling into the

Art Unit: 1651

mortar, in the device and method of Goldstein, because covered, cut tissue samples are carried and positioned above a sampling vessel and then forced into the vessel by contact from an impact lever, it is unlikely here as well that contaminants would fall into the sampling vessel. Thus, this is not an advantage which would distinguish Applicants' invention over the prior art.

Claims 1-2 and 5-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schütze et al. (US 5,998,129) in view of Goldstein et al. (WO 99/39176). Schütze discloses a device and method for capturing biological tissue samples (10) cut by laser microdissection in which a tissue sample is placed between a slide (2), as the top layer, and a slide support containing a hole (15), as the bottom layer. The slide support is mounted in a microscope table (3). The microscope table and slide support may be adjusted in an x-y plane by a drive mechanism to position the cut tissue sample and hole over a collection vessel (18). The light force from the laser pushes the cut sample in the direction of the laser, releasing it from the slide and forcing it into the collection vessel. The hole has a diameter larger than that of the collection vessel. The device also includes software and hardware so that images and locations of multiple positions in a tissue sample can be stored. The laser, slide and microscope table can then be repositioned multiple times so that multiple samples can be relocated, cut and collected (see col. 6, line 8, to col. 7, line 67, and Figure 5). Schütze does not disclose an impact lever with a flexible linking head for forcing a cut tissue sample into a collection vessel.

As discussed above, however, Goldstein discloses a device and method in which a cut tissue sample is forced into a collection vessel by the impact from an impact lever

Art Unit: 1651

with a linking head (see Figures 11 and 12). Goldstein teaches that its impact lever is an improvement over earlier technology in which samples were separated from their covering layer manually by excision with a scalpel, scissors or die punch and digestion by proteinase K (see p. 2, lines 12-22). Schütze mentions that earlier technology also included retrieving desired cells in a biological sample from a substrate by placing the sample in a micromanipulator and separating the desired cells with needles. This is a slow process that mechanically stresses the cells, that can introduce contamination and that cannot be practically performed on a large number of samples (see col. 1, lines 59-67, and col. 7, lines 38-43). Thus, one of ordinary skill in the art at the time that the invention was made would have been motivated to modify the device and method of Schütze by including an impact lever in the device to detach samples from the slide because Goldstein teaches that forces from the impact lever are superior to manual techniques for transferring cut samples to collection vessels. Schütze teaches that its computer-automated techniques for transferring cut samples to collection vessels are superior to manual manipulation with needles. Although the sample transfer and collection technique of Schütze does not disclose using an impact lever, one of ordinary skill in the art of laser microdissection would have recognized the propensity of cells for sticking to surfaces and that targeted cells separated by laser cutting might not always have been freed from their covering layer to fall into a collection vessel. Consequently, the artisan of ordinary skill would have recognized the need for second technique of applying force to a position on a slide to transfer a cut sample to a collection vessel. Thus, the skilled artisan would have been motivated to modify the device and method of

Schütze by including the impact lever of Goldstein for the advantages disclosed therein.

A holding of obviousness is therefore required.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson
Examiner
Art Unit 1651

rk
2004-11-02



FRANCISCO PRATS
PRIMARY EXAMINER